rior to DTIC alone (OR = 1.40, CI95%:1.10–1.79). Non-interferons were ineffective (OR = 1.24, CI95%:0.93–1.65). Interferons appeared to be effective adjunctive therapies (OR = 1.60, CI95%:1.03–2.50) with a survival of 10.5 ± 4.2 months. However, small (older) studies produced high rates while large (newer) studies found lower rates. **CONCLUSIONS:** Meta analysis of current publications demonstrated that standard treatment with DTIC produces response rates between 12.6 and 17.2. The addition of other treatments to DTIC offer no clinical advantage, except possibly interferons, but incremental advantages are modest at best. Studies were generally of poor quality. Effective treatments are needed to treat advanced melanoma.

CN2

USING PSYCHOMETRIC AND CLINIMETRIC TECHNIQUES TO SELECT ITEMS FOR USE IN A NEW INSTRUMENT TO MEASURE CANCER-RELATED FATIGUE

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OBJECTIVE: The aim of the present study was to develop a patient reported outcome (PRO) instrument which would be suitable for use in clinical practice to measure the intensity and impact of cancer-related fatigue (CRF), as well as patients' attitudes and beliefs regarding the condition. **METHODS:** Questionnaire content was generated from literature review, focus groups with oncology patients, and expert meetings with oncologists and specialists in the production of PRO instruments. Potential items were administered to oncology patients with CRF in a multi-center, cross-sectional, item reduction study. Patients answered all items twice to obtain data on both item frequency and importance using 5-point Likert-type scales. Item reduction was performed using a combination of clinimetric (calculation of impact score by multiplying frequency and importance scores for each item, expert opinion) and psychometric analysis (factor analysis, evaluation of scale internal consistency), and Item Response Theory (IRT) techniques. **RESULTS:** The initial pool of 75 items was administered to 238 cancer patients (mean age 57 years, 56% women, 30% breast cancer, 64% with metastasis, 46% with anemia). The 35 items with the lowest impact score were eliminated in clinimetric analysis; statistical analyses eliminated a further 15 items, and 13 items were eliminated on the basis of expert clinical opinion, supported by findings from the IRT analysis and item-scale correlations. The final measure includes 12 items. Factor analysis confirmed the presence of 3 dimensions: physical function (4 items), activities daily living (4 items) and beliefs/attitudes (4 items). Cronbach's alpha values for the overall score and individual dimensions were 0.92, 0.78, 0.85, and 0.81, respectively. **CONCLUSIONS:** The combination of methods for item reduction has led to the production of a new instrument with 12 items and 3 dimensions, which it is hoped will be suitable to measure aspects of CRF which are important in clinical practice.

CN3

PHARMACOECONOMIC (PE) ANALYSIS OF THE TREATMENT OF NON-SMALL CELL LUNG CANCER (NSCLC) IN THE NETHERLANDS DEMONSTRATES THAT ERLOTINIB DOMINATES DOCETAXEL AND IS COST-EFFECTIVE OVER BEST SUPPORTIVE CARE (BSC) WITHOUT NEED FOR PATIENT STRATIFICATION

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OBJECTIVE: A PE analysis was performed to support the reimbursement request of erlotinib in 2nd/3rd-line treatment of NSCLC in The Netherlands (NL). **METHODS:** Erlotinib and BSC efficacy data (based on the erlotinib registration study, BR.21) were used for this analysis. Chart reviews (n = 96) were conducted to obtain insight into health care utilisation (HCU) of stage IIIB/IV relapsed NSCLC. Charts from patients treated with docetaxel (n = 24) and BSC (n = 72) in 4 general and 1 academic hospital were used. The PE analysis was performed from the societal perspective and both outcomes and efficacy results were discounted at 4%. Official price lists (2004) were used and the price of erlotinib was set at €2184/150 mg/30 tablets. PE outcomes extrapolated to 3 years were evaluated using a Markov health-state model, adapted for NL. Outcomes and model assumptions were approved by an expert panel of 10 Dutch clinicians. **RESULTS:** The average treatment costs per patient in NL were €24,939 for docetaxel, €23,436 for erlotinib, and €15,450 for BSC. Life-years gained (LYG) were 0.84 years for docetaxel and erlotinib and 0.62 years for BSC, as per the BR.21 registration trial intent-to-treat population. The incremental cost-effectiveness ratio (ICER) for erlotinib vs BSC was €37,059/LYG (CI €12,621–€72,960) based on 4.3 month treatment duration. Erlotinib dominated docetaxel in all scenarios except when an unrealistically low docetaxel dose (110mg/cycle) was assumed. ICERs were sensitive to variations in length/frequency of hospitalizations and number of outpatient visits, illustrating the economic impact of erlotinib's generally mild adverse event profile. Erlotinib was cost-effective vs BSC in 80% of cases using a willingness-to-pay (WTP) threshold of €50,000/LYG. **CONCLUSIONS:** Treatment with erlotinib dominates docetaxel and is cost-effective vs BSC in NL. Based on the clinical efficacy and cost-effectiveness, erlotinib has received unrestricted reimbursement for relapsed NSCLC in NL without requirements for patient stratification.

CN4

COST-EFFECTIVENESS OF ERLOTINIB COMPARED WITH DOCETAXEL FOR THE TREATMENT OF RELAPSED NON-SMALL CELL LUNG CANCER (NSCLC) IN THE UK

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OBJECTIVE: To evaluate the cost-effectiveness of erlotinib compared to docetaxel for treating stage III/IV relapsed NSCLC from the UK NHS's perspective. **METHODS:** A cost-utility approach was taken; primary endpoint was cost per QALY. Baseline patient characteristics were based on trials BR.21 (erlotinib arm) and TAX317 (docetaxel arm). Equivalent overall survival was assumed; any bias from this assumption was expected to favour docetaxel. The model stratified patients into progression-free survival (PFS), progression and death. Time in each health state was adjusted for QoL (EQ-5D data), including the impact of adverse events (AEs) and formulation of therapy experienced in